510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K032804

B. Analyte:
Lupus

C. Type of Test:
Control

D. Applicant:
Precision BioLogic

E. Proprietary and Established Names:
CryoCheck Weak Positive Control

F. Regulatory Information:

1. Regulation section:
   21 CFR 864.5425
2. Classification:
   Class II
3. Product Code:
   GGC
4. Panel:
   81 Hematology

G. Intended Use:

1. Indication(s) for use:
   CryoCheck Weak Positive Control is prepared from human source plasma and is recommended for use as a positive control in assays for lupus anticoagulant.
2. Special condition for use statement(s):

3. Special instrument Requirements:

H. Device Description:

I. Substantial Equivalence Information:

1. Predicate device name(s):
   CryoCheck Positive Control
2. Predicate K number(s):
   K952623

3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Material	Human source	Same
Intended Use	Use as a positive control in assays for lupus anticoagulant	Same
Format	Frozen	Same
Differences		
Item	**Device**	**Predicate**
Potency	Weak Positive	Strong Positive

J. Standard/Guidance Document Referenced (if applicable):

K. Test Principle:

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. *Precision/Reproducibility:*
    Intra-Vial Precision (%CV)

    PT - 0.55% APTT - 0.62%
    b. *Linearity/assay reportable range:*

    c. *Traceability (controls, calibrators, or method):*

    d. *Detection limit:*

    e. *Analytical specificity:*

    f. *Assay cut-off:*

2. Comparison studies:
    a. *Method comparison with predicate device:*

    b. *Matrix comparison:*

3. Clinical studies:
    a. *Clinical sensitivity:*

    b. *Clinical specificity:*

    c. *Other clinical supportive data (when a and b are not applicable):*

4. Clinical cut-off:

5. Expected values/Reference range:

M. Conclusion:

Based on a review of the precision data, and device labeling I recommended that this device is found substantially equivalent to a legally marketed device.